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INOGEN, INC.

8 UNITED STATES DISTRICT COURT
9 SOUTHERN DISTRICT OF CALIFORNIA

10 INOGEN, INC., a Delaware corporation,

11
12 Plaintiff,

13 v.

14 SEQUAL TECHNOLOGIES, INC., a Delaware
corporation,

15 Defendant.
16

17 SEQUAL TECHNOLOGIES, INC., a Delaware
corporation,

18 Counterclaim Plaintiff,
19

20 v.

21 INOGEN, INC., a Delaware corporation,

22 Counterclaim Defendant.
23
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25
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27
28

CASE NO. 09CV2391 H (JMA)

**PLAINTIFF INOGEN'S RESPONSE
TO THE NEW EVIDENCE OFFERED
BY DEFENDANT SEQUAL IN ITS
REPLY**

DATE: 04/07/2010

TIME: 10:00 a.m.

ROOM: 13

JUDGE: Hon. Marilyn L. Huff

1 **I. INTRODUCTION**

2 Inogen identified in its opposition briefing numerous reasons why Defendant's Motion
3 for Summary Judgment must be denied. Inogen pointed out the various deficiencies in the
4 declarations relied on by Defendant. Now, Defendant has impermissibly attempted to cure some
5 of these deficiencies in its Reply. "It is well established that new arguments and evidence
6 presented for the first time in Reply are waived." *Docusign Inc. v. Sertifi Inc.* 468 F. Supp 2d
7 1305, 1307 (W.D. Wash 2006) (citing *United States v. Patterson*, 230 F.3d 1168, 1172 (9th Cir.
8 2000)). Accordingly, the following new declarations submitted for the first time with
9 Defendant's Reply should be stricken under Fed. R. Civ. P. 12(f):

- 10 1. Declaration of Danaher (Document No. 37-3)
11 2. Second Declaration of Ritter (Document No. 37-2)
12 3. Second Declaration of Bixby (Document No. 37-4)

13 In the alternative, Inogen respectfully requests this Court to consider Inogen's objections to this
14 new matter, and its own rebuttal evidence and arguments.

15 **II. THE DANAHER DECLARATION DOES NOT SAVE DEFENDANT'S MOTION**
16 **FOR NON-INFRINGEMENT OF THE '590 PATENT**

17 In support of its Motion for Summary Judgment of the '590 patent, Defendant's moving
18 papers relied on two exhibits – Exhibits 22 and 23. Exhibits 22 and 23 were submitted
19 unauthenticated with defendant's motion over Inogen's objection. [Evid. Objections ISO
20 Opposition at 7-9.] Defendant's Reply introduces a new declaration of Mr. Danaher attaching the
21 unauthenticated chart of Exhibit 23. Thus, the new declaration purports to authenticate Exhibit
22 23.¹ However, the declaration of Mr. Danaher (including the attached Exhibit A) is inadmissible
23 for at least two reasons: (1) it is untimely and (2) Mr. Danaher is not a proper lay witness or
24 expert.

25
26 ¹ Defendant has not even attempted to properly authenticate Exhibit 22. "It is well
27 established that unauthenticated documents cannot be considered on a motion for summary
28 judgment." *Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F. 2d 1542, 1550 (9th Cir.
1990). Accordingly, Exhibit 22 must be stricken.

1 **A. THE DANAHER DECLARATION IS INAPPROPRIATE FOR A REPLY**
 2 **BECAUSE IT OFFERS NEW EVIDENCE THAT SHOULD HAVE BEEN**
 3 **ADDRESSED IN DEFENDANT’S OPENING BRIEF**

4 An unauthenticated document cannot be considered on a motion for summary judgment.
 5 *Hal Roach Studios*, 896 F. 2d at 1550. Realizing this *after* filing its motion, Defendant has now
 6 attempted to authenticate Exhibit 23. But, its effort at this late stage is untimely because
 7 Defendant has attempted to cure an authentication problem in its Reply – an issue that was
 8 identified by Inogen – which it should have done in connection with its opening brief. Defendant
 9 has not even offered an explanation as to why it could not have offered Mr. Danaher’s declaration
 10 in an attempt to timely authenticate Exhibit 23 in support of its opening brief. Thus, the
 11 supplemental Danaher declaration “address[es] issues which should have been addressed in the
 12 opening brief, and the new evidence is inappropriate for Reply.” *DocuSign*, 468 F. Supp 2d at
 13 1307. Accordingly, Defendant should be precluded from relying on the newly filed Exhibit A
 14 because it is untimely. It should be stricken.

15 **B. THE DANAHER DECLARATION IS INADMISSIBLE BECAUSE HIS**
 16 **DECLARATION LACKS FOUNDATION FOR A LAY WITNESS AND**
 17 **MR. DANAHER IS NOT AN EXPERT IN MATERIAL**
 18 **CHARACTERIZATION**

19 Even if this Court permits Defendant to file the Danaher declaration late, Mr. Danaher
 20 cannot be qualified as a lay witness or expert. The Danaher declaration is not authenticated, lacks
 21 foundation and is inadmissible.

22 Mr. Danaher is not the correct lay witness. Rule 602 of the Federal Rules of Evidence
 23 requires that “[a] witness may not testify to a matter unless evidence is introduced sufficient to
 24 support a finding that the witness has personal knowledge of the matter.” The Committee Note for
 25 Rule 602 states:

26 [T]he rule requiring that a witness who testifies to a fact which can be perceived by
 27 the senses must have had an opportunity to observe, and must have actually
 28 observed the fact.²

Here, the salesman – Mr. Danaher – could not have actually conducted the test; he is not trained to
 do so. What is more, Mr. Danaher does not even allege that he actually observed someone else

² Federal Rules of Evidence, Notes of Advisory Committee on Rules for Rule 602.

1 perform the test that produced the results depicted in his Exhibit A. The testing most certainly
2 would have been conducted outside of the “business” areas where salesmen work and within the
3 technical areas of a lab. Thus, Exhibit A has not been properly authenticated by a lay witness, and
4 should be stricken. *Hal Roach Studios*, 896 F. 2d at 1551-2 (holding that because affiant did not
5 have personal knowledge necessary to authenticate document, District Court erred in considering
6 document on motion for summary judgment).

7 The absence of an authenticated declaration is particularly troubling here because
8 Defendant has not even identified who performed the testing at issue. Thus, not knowing who
9 conducted the test, what was tested, or what methods were used, Inogen is left to take for granted
10 the very testing that Defendant has relied on as its sole basis to support its summary judgment
11 motion on the issue. It is unfair to Inogen for Defendant to consistently withhold the methodology
12 it uses to form its conclusions, knowing that it can cure any deficiency at a later point in time.
13 Either Defendant does not know who performed the testing at issue, or has chosen to withhold the
14 identity of the person(s) knowledgeable on the issue from cross-examination by Inogen. Neither is
15 sufficient to excuse its failure to authenticate. The Defendant’s failure to produce an authenticated
16 declaration on the issue is fatal to its motion.

17 Mr. Danaher has not been qualified as an expert in material characterization. If
18 foundational facts demonstrating relevancy or qualification are not sufficiently established,
19 exclusion of proffered expert testimony is justified. *LuMetta v. U.S. Robotics, Inc.*, 824 F.2d 768,
20 771 (9th Cir. 1987). As stated in his declaration, Mr. Danaher is a “Senior Account Manager at
21 UOP LLC” who currently “manag[es] the sales account between UOP and SeQual” and has
22 “always” been on the business side, *i.e.*, the non-technical side. [Danaher Decl. ISO Reply at ¶ 2.]
23 Unlike Dr. Tiwari who has spent his entire career in the field, Mr. Danaher is not an expert in
24 material characterization. If he was, he would know that the method of “Inductively Coupled
25 Plasma” is not capable of determining whether the Oxysiv MDX adsorption layer contains a
26 lithium-exchanged FAU adsorbent that has less than .01% calcium and less than .01% magnesium.
27 [Tiwari Decl. ISO Opposition at ¶ 5.] Because Mr. Danaher is not an expert, he is not capable of
28 laying the necessary foundation for expert testimony, including the identification of exactly what

1 was tested and whether the methods used were reliably applied in this case. Fed. R. Evid. 702. In
2 fact, the Defendant has not even attempted to qualify an expert on the issue. Instead, Defendant
3 relies exclusively on impermissible attorney argument.

4 Exhibit A is clearly inadmissible as an improper form of expert and lay witness testimony
5 and must be stricken. As a result, the Defendant is left with no evidence on the issue.

6 **C. ONLY INOGEN HAS OFFERED ADMISSIBLE EVIDENCE ON THE**
7 **ISSUE OF INFRINGEMENT OF THE '590 PATENT**

8 Inogen has provided evidence in the form of the MSDS report that shows no calcium or
9 magnesium in the Oxysiv MDX adsorption layer. [Ex. 80 at 461.] The Defendant argued in its
10 Reply that the absence of calcium and magnesium from the MSDS report carries no weight
11 because MSDS reports are only required by OSHA for hazardous materials. [Reply at 2 (the
12 MSDS report "is not a listing of all ingredients; it is only a document required by OSHA for
13 hazardous materials.")] Although curiously not specifically stated, Defendant is inferring that
14 magnesium and calcium are present, but that the report omits them as ingredients because they are
15 not hazardous.

16 UOP, however, has a practice of reporting magnesium and calcium as ingredients when
17 present in a sample, as shown in the various MSDS reports for different UOP adsorbent materials
18 for medical oxygen concentrators. For example, the MSDS for UOP's Oxysiv 5XP and 5A reports
19 "magnesium oxide," and "calcium oxide", respectively, as ingredients. [Decl. of M. Bresnahan
20 ISO Inogen's Response to New Evidence at Exs. 84 & 85.] If the Oxysiv MDX adsorption layer
21 did contain magnesium or calcium, UOP would have listed them as ingredients – just as they did
22 for its Oxysiv 5A and Oxysiv 5 XP MSDS reports.

23 And, Defendant ignores the fact that the MSDS report for Oxysiv MDX lists water as an
24 ingredient! [Ex. 80 at 461.] Defendant has not even argued that water is only listed because it is
25 hazardous – because it is not. Thus, the admissible evidence, as opposed to Defendant's attorney
26 argument, indicates that the MSDS report for Oxysiv MDX is a list of ingredients that does not
27 contain magnesium or calcium. At a minimum, this raises a genuine issue of material fact on the
28 issue precluding summary judgment.

1 **III. THE SECOND RITTER DECLARATION DOES NOT SAVE DEFENDANT'S**
 2 **MOTION FOR NON-INFRINGEMENT OF THE '136 PATENT**

3 In support of its Motion for Summary Judgment, Defendant's Reply introduces a second
 4 declaration of Dr. Ritter. This declaration purports to operate in two ways. First, paragraphs 3 – 5
 5 of the second declaration are offered by Defendant to cure the violations of Fed R. Evid. 702
 6 (governing expert opinions) that plagues Dr. Ritter's first declaration. However, the declaration is
 7 filed too late for that purpose. Second, Defendant also relies on paragraphs 6 and 7 for providing
 8 yet another set of K and CCMTC values for the Eclipse. Yet, Dr. Ritter has once again failed to
 9 provide sufficient explanation to qualify his declaration as an expert opinion. Dr. Ritter' second
 10 declaration is inadmissible for both purposes.

11 **A. ¶¶ 3-5 OF THE SECOND RITTER DECLARATION ARE**
 12 **INADMISSABLE BECAUSE THEY OFFER NEW EVIDENCE THAT IS**
 13 **IRRELEVANT AND SHOULD HAVE BEEN ADDRESSED IN**
 14 **DEFENDANT'S OPENING BRIEF IF AT ALL**

15 Inogen identified that Dr. Ritter's first declaration is inadmissible for evidentiary reasons
 16 because he failed to lay proper foundation under Fed. R. Evid. 702. [Evid. Objections ISO
 17 Opposition at 9.] Having learned of these fatal flaws from Inogen's opposition, objections,
 18 declarations, and other filed papers, Defendant now attempts to cure these deficiencies in the form
 19 a second declaration. [2nd Ritter Decl. at ¶ 5 ("The procedure I used in my Declaration dated
 20 February 19, 2010 was the procedure described in Exhibits 81 and 82.")]. Thus, the supplemental
 21 declaration of Dr. Ritter addresses issues which should have been addressed in connection with
 22 Defendant's opening brief and, therefore, the new evidence is inappropriate for a Reply.
 23 *Docusign*, 468 F. Supp 2d at 1307. Defendant has not explained why Dr. Ritter could not have
 24 disclosed the model he used in his original declaration. This is particularly troubling here because
 25 his failure to do so forced Inogen to speculate as to the basis for Defendant's entire position as to
 26 why it does not infringe the '136 patent. Defendant should not be permitted to withhold
 27 information in its opening brief to its benefit, knowing all along that if necessary it can simply
 28 cure the deficiency in connection with its Reply. This is an abuse of the briefing process. The
 defendant should be precluded from relying on Dr. Ritter's newly filed second declaration to save
 its motion. This Court must strike paragraphs 3 – 5 of Dr. Ritter's second declaration.

1 However, even if this Court permits Defendant to rely on Dr. Ritter's second declaration,
 2 his declaration only clarifies that Dr. Ritter has in fact relied on the wrong model for determining
 3 K and CCMTC values of the '136 patent. Because Dr. Ritter relied on a model in his first
 4 declaration that is based on the concentration of nitrogen in the adsorbed phase rather than the gas
 5 phase, Dr. Ritter's first declaration does not provide K or CCMTC values within the meaning of
 6 the '136 patent. [Decl. of K. Knaebel ISO Opposition at ¶ 21.] And, Dr. Ritter's second
 7 declaration does not cure this fatal error, but confirms it. Thus, to the extent this Court determines
 8 that Dr. Ritter's late-filed second declaration has cured the deficiency of his first declaration –
 9 which is improper – Defendant has still not offered relevant evidence on the issue of infringement.

10 **B. ¶¶ 6-7 OF THE SECOND RITTER DECLARATION ARE INADMISSIBLE**
 11 **BECAUSE THEY FAIL TO PROVIDE PROPER FOUNDATION FOR AN**
EXPERT OPINION

12 “In the First and Federal Circuits, an expert's opinion expressed in an affidavit or a
 13 declaration, submitted for purposes of summary judgment, must be more than a conclusory
 14 assertion.” *Insight Tech., Inc. v. SureFire, LLC*, 618 F. Supp. 2d 114, 118 (D.N.H. 2009).
 15 (holding expert declaration that failed to provide factual basis for conclusions was insufficient to
 16 support a motion for summary judgment on the issue of infringement). Here, realizing that his
 17 first declaration relied on the wrong model for determining K and CCMTC values within the
 18 meaning of the '136 patent, Dr. Ritter provides a second set of calculations alleging to show what
 19 Defendant now believes to be the K values and CCMTC values of the Eclipse. However, Dr.
 20 Ritter has again failed to provide a complete disclosure of the actual methods that he used to
 21 determine the K and CCMTC values he identifies in paragraphs 6 and 7 of his second declaration.
 22 In addition, Dr. Ritter has failed to accurately and reliably apply Equation (2) of the '136 patent.
 23 Fed. R. Evid. 702 (expert testimony must be based on facts and the methods used must be reliably
 24 applied); *Insight Tech.*, 618 F. Supp. 2d at 118. In fact, as explained by Dr. Knaebel, there are at
 25 least three problems with Dr. Ritter's data and calculations rendering his results scientifically
 26 “implausible.” [Decl. of K. Knaebel ISO Inogen's Response to New Evidence at ¶¶ 8 - 13.] And
 27 so, here we are again – Inogen has been left to speculate as to the reasoning behind Dr. Ritter's
 28 conclusions. But, Defendant has now run out of time and cannot cure its second, deficient Ritter

1 declaration. The declaration must be stricken. In turn, this Court should deny Defendant's
2 Motion for Summary Judgment of non-infringement of the '136 patent.

3 **IV. THE SECOND BIXBY DECLARATION DOES NOT SAVE DEFENDANT'S**
4 **MOTION**

5 Defendant has filed yet another untimely, impermissible declaration, here, a second
6 declaration of Mr. Bixby. Inogen objected to the statements made by Mr. Bixby in his first
7 declaration on the basis that his statements are conclusory, lack evidentiary support, lack
8 foundation, are speculative, and/or are violative of the best evidence rule. [Evid. Objections ISO
9 Opposition at 10-14.] Mr. Bixby has not even attempted to cure the deficiencies of his first
10 declaration. Instead, Mr. Bixby rattles off another laundry list of objectionable statements. The
11 following table lists the objectionable statements in the Bixby declaration and the reasons that
12 such statements should not be considered by this Court:

<u>Second Declaration of Bixby</u>	<u>BASIS FOR STRIKING</u>
3. Oxysiv MDX, as received from the manufacturer, comes in a bead form with all aspects of the adsorbent in that bead – including any binder material and non-binder material in that adsorbent.	<ul style="list-style-type: none"> • This statement is an improper expert and lay opinion. Without establishing that Mr. Bixby has examined the material under a high powered electron microscope, how can Mr. Bixby possibly opine as to what are contained in a microscopic bead? • The statement is hearsay unqualified by an exception and Mr. Bixby lacks personal knowledge.
4. Prior to incoming air coming in contact with the Oxysiv MDX adsorbent in the Eclipse, the incoming air is pretreated to remove water.	<ul style="list-style-type: none"> • This statement is an improper expert and lay opinion. Mr. Bixby has not laid a proper foundation that he has ever examined Oxysiv MDX and established himself as an expert in such a way that would provide him with knowledge or understanding as to how the pretreatment layer of the Eclipse operates. • This statement is misleading under Fed. R. Evid. 403. A key difference between the Omni and the Eclipse is that the Eclipse does not contain activated alumina. Yet, Mr. Bixby leads the court to believe that the pretreatment layer of the Eclipse and Omni are the same, which is contrary to the evidence. • The statement is vague and ambiguous as to what is meant by "incoming air is pretreated"

1	<u>Second Declaration of Bixby</u>	<u>BASIS FOR STRIKING</u>
2		to remove water.” And, how much of the
3		water is removed? To the extent Mr. Bixby is
4		opining that any amount of water is removed
5		in a pretreatment layer during operation, the
6		opinion is objectionable as lacking foundation
7		for an expert opinion.
8		<ul style="list-style-type: none"> • The statement is hearsay unqualified by an
9		exception and Mr. Bixby lacks personal
10		knowledge.
11	5. During operation of the Eclipse, when	<ul style="list-style-type: none"> • This statement is an improper expert opinion
12	the incoming air is received by the Eclipse,	and lay opinion on the issue of how air
13	that air interacts with the entire Oxysiv	interacts within the device.
14	MDX adsorbent bead.	<ul style="list-style-type: none"> • This statement is misleading under Fed. R.
15		Evid. 403 to the extent it implies that the
16		binder material contained in the bead operates
17		to remove nitrogen from air. Rather, the
18		lithium-exchanged FAU contained in the
19		Oxysiv MDX adsorption layer is what
20		removes nitrogen from air.
21		<ul style="list-style-type: none"> • The statement is vague and ambiguous as to
22		what is meant by “incoming air interacts.” To
23		the extent Mr. Bixby is opining on the binding
24		of nitrogen to a zeolite, the opinion is
25		objectionable as lacking foundation for an
26		expert opinion.
27		<ul style="list-style-type: none"> • The statement is hearsay unqualified by an
28		exception and Mr. Bixby lacks personal
		knowledge.
	6. The Eclipse 2® has the same adsorbent,	<ul style="list-style-type: none"> • Mr. Bixby has not laid a proper foundation
	the flow rates and the flow volume as the	that he has ever examined an Eclipse and
	Eclipse®.	established himself as an expert in such a way
		that would provide him with knowledge or
		understanding as to how any Eclipse versions
		operate.
		<ul style="list-style-type: none"> • This statement is potentially prejudicial under
		Fed. R. Evid. 403 because SeQual is
		comparing two versions of the Eclipse, yet
		Inogen has specifically requested that it
		examine and test the Eclipse and Eclipse 2 so
		that it can make its own determination as to
		the similarities between the devices. Inogen
		reserves its right once it has had the
		opportunity to test the various working

<u>Second Declaration of Bixby</u>	<u>BASIS FOR STRIKING</u>
	<p>versions to challenge that the Eclipse and the Eclipse 2 have a different adsorbent, flow rates and flow volume, or that other features between the versions are the same or different.</p> <ul style="list-style-type: none"> • This statement is vague and ambiguous, particularly with respect to what is meant by “adsorbent,” “flow rates,” and “flow volume.” For one, flow rates could refer to the product flow rates, or could refer to the rate that the compressed air that is introduced into the adsorber vessels of the Eclipse versions. • The statement is hearsay unqualified by an exception and Mr. Bixby lacks personal knowledge.

Accordingly, Inogen requests that this court not consider Mr. Bixby’s objectionable statements made in either his first or second declarations to support Defendant’s Motion for Summary Judgment.

V. CONCLUSION

Defendant has not met its burden to prevail on its Motion for Summary Judgment of invalidity of all four patents and non-infringement of the ‘136 and ‘590 patents. Even if Defendant did meet its burden, Inogen has presented at least a genuine issue of material fact with respect to each issue. This Court should deny Defendant’s motion.

Dated: April 6, 2010

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CERTIFICATE OF SERVICE

On April 6, 2010, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

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